IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MLI RX LLC, AMERISOURCEBERGEN CORP., AMERISOURCEBERGEN DRUG CORP., H.D. SMITH, LLC, VALLEY WHOLESALE DRUG CO., LLC (SUBSIDIARY OF H.D. SMITH, LLC), CARDINAL HEALTH, INC., CARDINAL HEALTH P.R. 120, INC., THE HARVARD DRUG GROUP, L.L.C., CARDINAL HEALTH 110 LLC, MCKESSON CORPORATION, BURLINGTON DRUG COMPANY, INC., DAKOTA DRUG, INC., NORTH CAROLINA MUTUAL WHOLESALE DRUG COMPANY, PRESCRIPTION SUPPLY, INC., J M SMITH CORPORATION D/B/A SMITH DRUG COMPANY, VALUE DRUG COMPANY, Plaintiffs, v. GLAXOSMITHKLINE LLC f/k/a SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. COMPLAINT JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs MLI Rx LLC, AmerisourceBergen Corp., AmerisourceBergen Drug Corp., H.D. Smith, LLC, Valley Wholesale Drug Co., LLC (subsidiary of H.D. Smith, LLC), Cardinal Health, Inc., Cardinal Health P.R. 120, Inc., The Harvard Drug Group, L.L.C., Cardinal Health 110 LLC, McKesson Corporation, Burlington Drug Company, Inc., Dakota Drug, Inc., North

Carolina Mutual Wholesale Drug Company, Prescription Supply, Inc., J M Smith Corporation d/b/a Smith Drug Company, and Value Drug Company (collectively, "Plaintiffs"), by and through their undersigned attorneys, bring this action against Defendants GlaxoSmithKline LLC f/k/a SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and its subsidiary Teva Pharmaceuticals USA, Inc. ("Teva USA") (jointly, "Teva") (all defendants collectively, "Defendants"). Plaintiffs allege as follows based on: (a) personal knowledge; (b) the investigations of counsel, including review of various pleadings and rulings in *SmithKline Beecham Corp. v. Teva Pharmaceuticals USA, Inc.*, United States District Court, District of New Jersey, Nos. 02-cv-3779 and 02-cv-4537, and *Teva Pharmaceutical Industries Ltd., et. al v. SmithKline Beecham Corporation*, United States District Court, District of New Jersey, No. 08-cv-03706, discussed herein; and (c) information and belief.

I. NATURE OF THE ACTION

1. This antitrust action challenges Defendants' anticompetitive conduct that delayed generic competition in the market for Lamictal tablet products ("Lamictal Tablets"), a prescription drug used to treat epilepsy, bipolar disorder and other medical conditions, and improperly manipulated the Hatch-Waxman Act to impede, rather than promote, generic competition as intended by the statute.

2. Under the Federal Food, Drug and Cosmetics Act of 1938, 21 U.S.C. §§ 301-392 ("FD&C Act"), a manufacturer that creates a new drug must obtain Food and Drug Administration ("FDA") approval to sell the new drug by filing a New Drug Application ("NDA") which includes, among other things, submission of clinical studies concerning the safety and efficacy of the drug, as well as any information on applicable patents.

3. Recognizing the great savings available to purchasers by the presence of generic drugs, Congress in 1984 passed the "Hatch-Waxman Act" (officially called the Drug Price

Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)) ("Hatch-Waxman"), which amended the FD&C Act to facilitate and expedite the approval of generic drugs. Prior to these amendments, competitors seeking to sell a generic version of a brand name drug needed to go through the lengthy and costly process of filing their own NDA to obtain FDA approval. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by providing an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA"). A proposed generic's ANDA is not required to contain the same type of independent clinical studies to demonstrate safety and efficacy as contained in an NDA, but is allowed to make that showing by demonstrating that it is therapeutically and pharmaceutically equivalent to the corresponding brand drug.

4. "AB-rated" generic versions ("generics") of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. Specifically, the FDA has determined that an AB-rated generic product is therapeutically and pharmaceutically equivalent to the brand-name counterpart. This means that the generic version has the same active ingredient, strength, route of administration, and dosage form as the branded counterpart, and that the active ingredient of the generic drug remains in the bloodstream of the patient for the same relative amount of time in the same relative proportion as the branded drug.

5. The only material difference between generics and brand name drugs is their price. Generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both: (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings; and (b) a

serious threat to the monopoly power and profits of the manufacturer of a brand name drug facing generic competition. Because of the significant price savings from the use of generics, in most states the laws and regulations allow (and many states require) pharmacists to automatically substitute an AB-rated generic version of a drug for the brand name drug in most instances.

6. As part of the ANDA process a generic manufacturer must certify that the proposed generic drug does not violate any patents that claim the brand name drug, which are identified in an FDA publication called the Orange Book. When the ANDA applicant takes the position that any listed patent(s) is invalid or will not be infringed by the generic product, it must file a Paragraph IV certification. This is especially significant because, if a generic files a Paragraph IV certification, the brand-name manufacturer has the opportunity to slow down the approval process of the generic drug. If the patent owner files a patent infringement action within 45 days after receiving notice of the generic manufacturer's Paragraph IV certification, then the FDA is automatically enjoined from granting final approval to the ANDA until the earlier of either 30 months or the issuance of a district court decision that the patent is invalid, unenforceable, or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii).

7. The Hatch-Waxman Act encourages challenges to branded drug patents by granting the first Paragraph IV ANDA filer up to 180 days to exclusively market the generic version of the drug, during which time the FDA will not grant final approval to any other generic manufacturer's ANDA for the same generic drug. As explained in paragraph 12 below, the 180 days of marketing exclusivity granted to the first Paragraph IV ANDA filer is a significant and potentially highly profitable benefit.

8. Until an AB-rated generic enters the market, there is no drug or other product that price competes with the branded drug, and therefore, the brand manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its branded sales. Consequently, brand manufacturers have a strong incentive to engage in conduct, including the conduct alleged herein, to delay generic competition.

9. One tactic that brand manufacturers use to delay generic competition is to file a patent infringement suit against the generic (even if it is likely that the patent at issue is invalid, unenforceable, or not infringed) to trigger the automatic injunction that prevents the FDA from approving a generic ANDA for up to 30 months. Then, upon recognizing the significant risk that the patent infringement claims will not succeed, the branded manufacturer will give the generic manufacturer significant financial inducements to accept a settlement in which the generic agrees to stay off the market for a much longer time than the strength of the patent warrants. In such instances, the generic's agreement to stay off the market is not due to the patent's scope or strength but simply because the generic has agreed to not compete for a period of time in exchange for valuable financial inducements that the brand-name company gives.

10. This suit concerns GSK's use of such improper tactics (and others) to prevent and/or impede generic competition for Lamictal Tablets, which contains the active ingredient lamotrigine. Shortly after GSK launched Lamictal Tablets in or about 1994, the drug quickly became one of GSK's top-grossing products. GSK's sales of Lamictal Tablets in the United States were in excess of $2 billion during the twelve months ending March 2008.

11. Teva, the largest generic pharmaceutical manufacturer in the world, recognized the huge market potential for Lamictal, and in April 2002, was the first generic firm to file ANDAs with the FDA seeking approval to market generic versions of Lamictal Tablets and

Lamictal chewable dispersible tablets ("Lamictal Chewables"). Teva's ANDAs contained Paragraph IV certifications that Teva's proposed generics did not infringe any valid or otherwise enforceable patent(s) listed in the Orange Book as covering Lamictal Tablets or Lamictal Chewables, including specifically U.S. Patent No. 4,602,017 ("the '017 patent"). GSK is the assignee of the '017 patent, which claims 3,5-Diamino-6(2,3-dichlorophenyl)-1,2,4- triazine, the active ingredient in Lamictal Tablets and Lamictal Chewables (which is also referred to as "lamotrigine") as well as certain methods of using lamotrigine. The '017 patent had an expiration date of July 22, 2008.

12. As the first Paragraph IV ANDA filer, Teva stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. §355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic Lamictal product ("first-filer"). The 180-day exclusivity period could potentially provide Teva with an extremely valuable competitive advantage versus other generics which would enable Teva to have 100% of the generic sales during this 180-day period and charge higher generic prices during this period than in a market with multiple generics. Furthermore, it is well-known in the industry that those generics which are able to take advantage of the 180-day exclusivity periods are able to get a "first mover advantage" resulting in the permanent retention of a larger market share than later entrants, even after other generics enter the market. However, the 180-day exclusivity period does not bar an NDA holder from selling an "authorized generic" or licensing their product to another company to sell an "authorized generic."[1] If a brand company chooses to counter or preempt the initial generic entry with an authorized generic, it

[1] An authorized generic is simply the brand product sold under generic trade dress at a cheaper price than the brand. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.,* 791 F.3d 388 (3d Cir. 2015) (describing authorized generics and the role of authorized generics in pharmaceutical competition).

could greatly diminish the profit potential of the first ANDA filers' product, which otherwise could have been the sole generic on the market.

13. In August 2002, GSK sued Teva for alleged infringement of the '017 patent based on Teva's Paragraph IV ANDAs seeking approval to market generic versions of Lamictal Tablets and Lamictal Chewables. The filing of these suits triggered an automatic stay of approval of Teva's ANDAs for up to 30 months. The cases were subsequently consolidated (the "Patent Litigation") and eventually proceeded to a five-day bench trial before the Honorable John W. Bissell in January 2005. On the final day of trial, Judge Bissell ruled that Teva "prove[d] by clear and convincing evidence that Claim 1 [of the '017 patent], the alleged invention of lamotrigine, is invalid," and informed the parties that he would deliberate over the course of the next week on the remaining claims, and that a ruling on those claims would be forthcoming.

14. Having already invalidated the claim of the '017 patent that covered the active ingredient of Lamictal, i.e., lamotrigine, it was highly likely that Teva would prevail with respect to the remaining patent claims. These claims were extremely weak in view of Judge Bissell's ruling that Claim 1 was invalid. However, GSK and Teva faced the loss of significant future profits if the court invalidated the '017 patent's remaining claims at issue. GSK stood to lose its patent protection preventing generic competition for Lamictal Tablets and Lamictal Chewables, which would result in a dramatic reduction in GSK's future revenue for both products.

15. Teva also faced a quandary because it knew that its ANDAs for both Lamictal Tablets and Lamictal Chewables were not ready for final approval from the FDA. A final decision in its favor on the '017 patent would have been a Pyrrhic victory for Teva, because it would trigger the running of its 180-day exclusivity period before Teva was ready to profit from

its success. Under Hatch-Waxman, Teva's 180-day exclusivity period for generic versions of Lamictal Tablets and Lamictal Chewables would be triggered by the earlier of either: (a) Teva's market entry or (b) a court-entered final decision that the patent(s) subject to the Paragraph IV certification was invalid, unenforceable, and/or not infringed. While Hatch-Waxman creates an opportunity for the first-filer of a Paragraph IV certification (the "first filer") to have up to 180 days of exclusivity versus other generics, Hatch-Waxman does not guarantee a first filer the right to profit from all (or any) of the 180-day exclusivity period. That is so because, if, for instance, the 180-day period is triggered by a final court decision, but the first filer has not yet obtained final approval from the FDA to market its generic product, the 180-day period may begin and end before the first filer can enjoy any actual sales of its product during that time.

16. Because the FDA had not yet granted Teva approval to market generic versions of Lamictal Tablets or Lamictal Chewables in January 2005, Teva faced the risk that it would not be able to reap any of the monetary rewards that come with being the first ANDA filer before the 180-day exclusivity period expired. If Teva's 180-day exclusivity period expired before its generic Lamictal Tablet and Lamictal Chewable products were approved for sale, other competing generic firms with approved AB-rated products might be able to enter the market at the same time as (or even before) Teva. This would mean that not only would Teva not be able to garner the full profits of the 180-day period, but another generic could gain the long-term "first-mover" advantage.

17. Thus, faced with the risk that the court would invalidate the remaining claims of the '017 patent, GSK had an interest in delaying Teva's generic Lamictal Tablet entry for as long as possible so that GSK could continue to earn monopoly profits on Lamictal Tablets. Teva also

had an interest in delaying a final court decision finding the '017 patent invalid until it was ready to take advantage of its valuable 180-day period.

18. Recognizing the severe financial risks to both parties, on February 16, 2005, the Defendants entered into a Settlement Agreement and a License and Supply Agreement ("License Agreement") (jointly, the "Agreements"). Under the Agreements, Teva agreed to not enter the market with a generic version of GSK's $2 billion-a-year Lamictal Tablets product until the July 2008 expiration date of the '017 patent. Thus, even though in January 2005, Teva had already succeeded in invalidating Claim 1 of the '017 patent covering the active ingredient of Lamictal, and even though the remaining claims of the patent at issue were extremely weak and highly likely to be held invalid, the Agreements provided no procompetitive benefit because they delayed Teva's market entry of generic versions of Lamictal Tablets until after the expiration of the '017 patent. As to Lamictal Chewables, GSK granted Teva permission to sell a limited quantity of GSK-supplied Lamictal Chewables product beginning June 2005, and an exclusive license to market generic Lamictal Chewables upon receiving final FDA approval for the entire term of the '017 patent including any period of Pediatric Exclusivity GSK would obtain. Also, during the period after the expiration of the '017 patent and any GSK-held regulatory exclusivities that could have prevented Teva from coming to market, GSK agreed not to launch less expensive authorized generic Lamictal Tablets in competition with Teva. These payments were worth hundreds of millions of dollars to Teva, were far larger than any litigation costs saved by GSK by settling, and there are no redeeming procompetitive justifications for these payments. In exchange for these payments, Teva agreed to abandon its patent challenge and delay its launch of generic Lamictal for almost 3½ years, until after GSK's '017 patent expired

on July 22, 2008. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.,* 791 F.3d 388 (3d Cir. 2015).

19. The Agreements benefitted Teva because GSK's agreement not to launch authorized generic Lamictal Tablets allowed Teva to enjoy *100* percent of generic Lamictal sales rather than just 50 percent during its 180-day exclusivity period (absent GSK's promise not to launch authorized generic Lamictal Tablets, Teva would have lost half the sales to the authorized generic), and also prevented Teva's generic prices from falling due to competition from an authorized generic. GSK's promise not to launch authorized generic Lamictal Tablets during Teva's 180-day exclusivity period also allowed Teva to maximize its longer-term profits by obtaining the "first mover advantage" noted above. The Agreements also benefitted Teva by ensuring that there would not be a final court decision invalidating the patent before Teva was ready to use its 180-day exclusivity for generic Lamictal Tablets (along with other benefits discussed below). Teva also benefited from GSK's agreement to allow Teva to sell a limited quantity of GSK-supplied Lamictal Chewables product beginning in June 2005, and an exclusive license to market generic Lamictal Chewables upon receiving final FDA approval for the entire term of the '017 patent including any period of Pediatric Exclusivity GSK would obtain.

20. The Agreements benefitted GSK by delaying market entry of less-expensive generic versions of Lamictal Tablets until the expiration of the '017 patent, ensuring that Teva would not enter upon final FDA approval of its ANDA in the event that occurred prior to the end of the patent term. GSK also benefitted in a broader sense in that the Agreements as a whole delayed not only the entry of Teva's generic Lamictal Tablet product, but other generics as well because without a court ruling holding the patent invalid or not infringed, no other generic could enter until Teva exercised its 180-day exclusivity period.

21. Thus, by and through these Agreements, Teva and GSK afforded themselves a guarantee of higher revenues during these periods of time which resulted in anticompetitive overcharges being thrust upon purchasers.

22. In exchange for its agreement to delay entry of its generic Lamictal Tablets, Teva received substantial financial inducements that went beyond what Teva could have achieved if it was fully successful in the patent litigation. GSK and Teva have expressly stated that the inducements discussed below were part of the "consideration" that GSK offered Teva "in reaching agreement to settle."

23. First, Teva was permitted to sell limited amounts of a generic version of the Lamictal Chewable product, starting on June 1, 2005. In pleadings from a subsequent litigation between the Defendants, GSK acknowledged that permitting Teva to market a generic version of the Lamictal Chewable product beginning in June 2005 was a benefit given to Teva in exchange for Teva's agreement to delay marketing of its generic version of the far more lucrative Lamictal Tablets product until the expiration date of the '017 patent in July 2008. In effect, even though Claim 1 of the '017 patent was held invalid and Teva was very likely to prevail as to the remaining asserted claims, Teva agreed not to market a competing generic Lamictal Tablet product for the entire patent term. As indicated below, any Pediatric Exclusivity GSK obtained could not further delay Teva's generic entry unless there was a ruling by Judge Bissell that the '017 patent was valid and infringed by Teva's proposed generics.[2]

[2] Pediatric Exclusivity attaches on an ANDA-by-ANDA basis. *See* paragraph 57 below. Thus, even though Pediatric Exclusivity would not delay entry of Teva's proposed generics, that exclusivity (depending on the circumstances) could delay final approval of other generic manufacturers' ANDAs.

24. Significantly, even though both the Lamictal Tablet and Lamictal Chewable products were subject to the same patent claims (and Teva's chances of litigation success were the same for both products) Teva and GSK agreed that Teva would enter the market for the less profitable Lamictal Chewable product three months after the settlement (in June 2005), but that Teva would wait the entire patent term – which amounted to three or more years – to launch a generic version of the exponentially more profitable Lamictal Tablet product. The disparate treatment and entry dates that GSK and Teva negotiated for the two products (both of which were subject to the exact same patent claims and litigation risks) reflects the fact that the parties did not choose (or even attempt to choose) entry dates for the two products that reasonably reflected the probability that the asserted claims of the '017 patent were invalid. Rather, the disparate entry dates reflect the reality that Teva was given financial inducements to delay entry of its generic Lamictal Tablet product, one of which was GSK's agreement to allow Teva to sell a limited quantity of GSK-supplied Lamictal Chewables beginning no later than June 2005. While the negotiated deal benefitted Teva and GSK, the deal was not structured with any concern or interest for purchasers or consumers who need treatment for epilepsy, bipolar disorder, and other medical conditions at lower prices. The purchaser/consumer benefits gained by the entry of Teva's generic Lamictal Chewable in June 2005 pale in comparison to the purchaser/consumer harm incurred by the anticompetitive three-year delay in the entry of Teva's less-expensive generic version of Lamictal Tablets, and any purchaser/consumer benefits occurred in the market for Lamictal Chewables, which is a different market than the market for Lamictal Tablets, where the significant anticompetitive effects of the Agreements occurred.

25. Teva sought (and GSK gave) a second inducement to Teva to delay its entry of generic Lamictal Tablets: that GSK agreed to refrain from launching its own competing

authorized generic versions of Lamictal Tablets and Lamictal Chewables until January 2009 (i.e., 180 days after Teva was on the market with a generic version of Lamictal Tablets, and over three years after Teva was on the market with a generic version of Lamictal Chewables). This inducement was unquestionably beyond the exclusionary scope of the patent because Teva and GSK agreed not to compete with respect to generic products during a period when: (a) the '017 patent had expired and there were no GSK-held regulatory exclusivities that could bar Teva from coming to market; and (b) there were no patents or regulatory exclusivities that would bar GSK from launching an authorized generic product. Nothing in Hatch-Waxman would allow Teva's first-filer exclusivity to bar GSK from launching its own authorized generic versions of Lamictal Tablets and Lamictal Chewables during Teva's exclusivity periods. Furthermore, because Teva filed and maintained a Paragraph IV certification, any Pediatric Exclusivity that GSK later obtained could not delay Teva's ability to market Lamictal Tablets or Chewables after the expiration of the '017 patent term. As alleged below, but for the Agreements, GSK had an incentive to launch its own authorized generic version of Lamictal Tablets and Chewables, and has a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. Absent GSK's promise not to launch authorized generic Lamictal Tablets prior to January 2009, GSK would have launched generic Lamictal Tablets earlier, at or around the same time that Teva launched generic Lamictal Tablets. GSK's agreement not to launch authorized generic Lamictal Tablets until January 2009 was extremely valuable to Teva because it allowed Teva to enjoy 100 percent of generic Lamictal Tablets sales rather than just 50 percent during its 180-day exclusivity period (absent GSK's promise not to launch authorized generic Tablets promise, Teva would have lost

half the sales to an authorized generic), and prevented Teva's generic prices from falling due to competition from authorized generic Lamictal Tablets.

26. A 2012 FDA list of authorized generics shows that between January 1, 1999 and January 9, 2012, GSK launched authorized generics when faced with generic competition to at least ten of its branded pharmaceuticals products, including: Augmentin and Cutivate in 2003; Amoxil, Paxil, and Wellbutrin SR in 2004; Retrovir in 2005; Flonase and Zantac in 2006; Imitrex in 2007; and Paxil CR in 2010. Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.pdf. According to a Federal Trade Commission ("FTC") study on authorized generics, of both brand and generic companies, GSK launched the second highest number of authorized generics from the years 2001 to 2008. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, August 2011, at 16, available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-termeffects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-shortterm-effects-and-long-term-impact-report-federal-trade-commission.pdf.

27. The FTC and other government entities have recognized that the presence of an authorized generic significantly benefits purchasers by both increasing purchaser choices and also creating price competition which reduces generic prices during the 180-day period. By agreeing to not exercise its lawful right to launch authorized generics until January 2009, GSK was illegally agreeing to restrain or limit its ability to compete during this period.

28. As to Lamictal Tablets, absent the anticompetitive inducements that GSK gave to Teva to delay Teva's launch of its generic version of Lamictal Tablets, Teva would have pressed for (and the parties would have agreed to) an agreement without a large payment from GSK to

Teva, which agreement would have allowed Teva to come to market with its generic Lamictal Tablets earlier than the Agreements allowed. As alleged in more detail below, Teva has admitted that the agreement that GSK would not launch its own authorized generic was "critical here because the benefit conferred to Teva from this Settlement was of such a short duration." Alternatively, assuming there would have been no reverse payment-free settlement between the Defendants, the parties would have continued to litigate and Teva would have prevailed, and launched generic Lamictal Tablets immediately thereafter. In sum, "but for" the anticompetitive Agreements between the Defendants, generic competition in the market for Lamictal Tablets would have occurred sooner and would have resulted in substantial savings to the Plaintiffs.

29. The Agreements caused illegal anticompetitive harm to competition and to the direct purchasers of Lamictal Tablets and/or Teva's generic version of Lamictal Tablet, including the Plaintiffs, by causing them to pay higher, artificially-inflated prices for those products than they otherwise would have absent the conduct alleged herein. Plaintiffs were injured and sustained damages in the form of overcharges for branded and generic forms of Lamictal Tablets as a direct result of GSK and Teva's unlawful Agreements that accompanied the settlement of the '017 patent litigation. This civil antitrust case seeks overcharges (trebled) paid by Plaintiffs.

II. JURISDICTION AND VENUE

30. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Plaintiffs resulting from violations by Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

31. The Defendants named herein are found or transact business within this judicial district, and the interstate trade and commerce hereinafter described is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. STATUTE OF LIMITATIONS TOLLING

32. There is statute of limitations tolling pursuant to *American Pipe & Const. Co. v. Utah*, 414 U.S. 538 (1974) and *Crown, Cork & Seal Company, Inc. v. Parker*, 462 U.S. 345 (1983), which hold that the filing of a class action tolls the running of the statute of limitations for absent class members to bring individual suits.

33. The first private class action complaint on behalf of a putative class of direct purchasers of Lamictal against SmithKline Beecham Corporation d/b/a GlaxoSmithKline (n/k/a GlaxoSmithKline LLC), Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. was filed on February 17, 2012 in the District of New Jersey (*see* Case No. 2:12-cv-000995 (D.N.J.) (ECF No. 1)), which was followed shortly thereafter by additional direct purchaser class actions in that district. A consolidated class action complaint was then filed on June 25, 2012. *See id.* at ECF No. 55. On December 12, 2018, a direct purchaser class was certified in the District of New Jersey. *See id.* at ECF Nos. 428-29. On appeal, the Third Circuit vacated the certification of a direct purchaser class and remanded to the District of New Jersey. *See In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184 (3d Cir. 2020). On February 1, 2023, the District of New Jersey denied a renewed motion for the certification of a direct purchaser class. *See* Case No. 2:12-cv-000995 (D.N.J.) (ECF Nos. 553-54).

IV. PARTIES

34. Plaintiff MLI Rx LLC, a limited liability company organized under the law of the

state of New Jersey, is the successor-in-interest to and assignee of the claims of Miami Luken, Inc., a corporation formed and existing under the laws of the state of Ohio with a principal place of business in Shaker Heights, Ohio. Miami Luken, Inc. purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

35. Plaintiff AmerisourceBergen Corp. ("ABC") is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 1 West First Avenue, Conshohocken, Pennsylvania 19428. ABC subsidiaries purchased branded and generic Lamictal Tablets directly from GSK and Teva, and were injured by the illegal conduct described herein by paying overcharges. ABC also is asserting a claim for overcharges on behalf of Bellco Corporation, which purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

36. Plaintiff AmerisourceBergen Drug Corporation ("ABDC"), a wholly owned subsidiary of ABC, is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 1 West First Avenue, Conshohocken, Pennsylvania 19428. ABDC purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges. ABDC also is asserting a claim for overcharges on behalf of Bellco Corporation, which purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

37. Plaintiff H.D. Smith, LLC, a subsidiary of ABC, is organized under the laws of Delaware with a principal place of business at 3063 Fiat Avenue, Springfield, IL 62703. H.D.

Smith, LLC purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

38. Plaintiff Valley Wholesale Drug Co., LLC, a subsidiary of H.D. Smith, LLC, is organized under the laws of Delaware with a principal place of business at 1401 W Fremont Street, P.O. Box 2065, Stockton, CA 95203. Valley Wholesale Drug Co., LLC purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

39. Plaintiff Cardinal Health, Inc. is incorporated in Ohio with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017. Cardinal Health, Inc., itself and/or through one or more of its subsidiaries, purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

40. Plaintiff Cardinal Health P.R. 120, Inc. ("Cardinal Health P.R.") is a wholly owned subsidiary of Cardinal Health, Inc., and a corporation formed and existing under the laws of the territory of Puerto Rico with a principal place of business at 165 Km 2.4 Edificio 10, Guaynabo, Puerto Rico 00965. Cardinal Health P.R. purchased branded and/or generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

41. Plaintiff The Harvard Drug Group, L.L.C. ("Harvard"), is a wholly owned subsidiary of Generic Drug Holdings, LLC, which is a wholly-owned subsidiary of HDG Acquisition, LLC, which is a wholly-owned subsidiary of Cardinal Health 110, LLC, which is a wholly-owned subsidiary of Cardinal Health, Inc. Harvard is a limited liability company organized under the laws of Michigan with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. Harvard purchased branded and generic Lamictal Tablets

directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

42. Plaintiff Cardinal Health 110 LLC is organized under the laws of Delaware with a principal place of business at 7000 Cardinal Place, Dublin, OH 43017. Cardinal Health 110 LLC, including through Dik Drug Company, LLC and Kinray, Inc., purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges. Cardinal Health 110 LLC also is asserting a claim for overcharges on behalf of Dik Drug Company, LLC and Kinray, Inc., which purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

43. Plaintiff McKesson Corporation is incorporated in Delaware with a principal place of business at 6555 State Hwy. 161, Irving, Texas 75039. McKesson Corporation purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

44. Plaintiff Burlington Drug Company, Inc. ("Burlington Drug") is incorporated in Vermont with a principal place of business at 91 Catamount Drive, Milton, Vermont 05486. Burlington Drug purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

45. Plaintiff Dakota Drug, Inc. ("Dakota Drug") is incorporated in North Dakota with a principal place of business at 1101 Lund Blvd., Anoka, Minnesota 55303. Dakota Drug purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

46. Plaintiff North Carolina Mutual Wholesale Drug Company ("Mutual Drug") is incorporated in North Carolina with a principal place of business at 816 Ellis Road, Durham, North Carolina 27703. Mutual Drug purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

47. Plaintiff Prescription Supply, Inc. ("Prescription Supply") is incorporated in Ohio with a principal place of business at 2233 Tracy Road, Northwood, Ohio 43619. Prescription Supply purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

48. J M Smith Corporation d/b/a Smith Drug Company ("Smith Drug") is incorporated in South Carolina with a principal place of business at 9098 Fairforest Road, Spartanburg, South Carolina 29301. Smith Drug purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

49. Plaintiff Value Drug Company ("Value Drug") is incorporated in Pennsylvania with a principal place of business at 195 Theater Drive, Duncansville, Pennsylvania 16635. Value Drug purchased branded and generic Lamictal Tablets directly from GSK and Teva, and was injured by the illegal conduct described herein by paying overcharges.

50. Defendant GlaxoSmithKline LLC f/k/a SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a limited liability company organized under the laws of Delaware, with principal places of business at 2929 Walnut Street, Ste. 1700, Philadelphia, Pennsylvania 19104, and 410 Blackwell Street, Durham, NC 27701. GSK is in the business of, among other things,

developing, manufacturing, distributing, advertising, and selling branded Lamictal Tablets throughout the United States.

51. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of the State of Israel with headquarters at 124 Dvora HaNevi'a Street, Tel Aviv 6944020, Israel. Teva Ltd. is the ultimate parent company of Teva USA.

52. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is incorporated under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva USA develops, manufactures, and sells generic products in the United States. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

53. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA began selling in the United States in July 2008, and has sold generic lamotrigine chewables in the United States beginning in June 2005.

V. FACTUAL ALLEGATIONS

A. The Defendants' Products and the Nature of Sales of Generic Equivalent Products

54. GSK sells Lamictal Tablets in strengths of 25 mg, 100 mg, 150 mg, and 200 mg pursuant to New Drug Application No. 20-241, which was approved by the FDA in 1994. GSK sells Lamictal Chewables in strengths of 2 mg, 5 mg, and 25 mg pursuant to New Drug Application No. 20-764, which was approved by the FDA in August 1998. For the twelve months ending March 2008, GSK's sales of Lamictal Tablets in the United States exceeded $2 billion, according to IMS (now IQVIA) data. The low-dosage strength Lamictal Chewable product had annual domestic sales of about $50 million in the twelve months preceding the market entry of generic chewables in 2005.

55. Upon receiving FDA approval of its NDA for Lamictal Tablets on December 27, 1994, GSK was awarded a five-year new chemical entity ("NCE") exclusivity, which expired on or about December 27, 1999. During this five-year period, the FDA could not grant final approval to any ANDA, meaning GSK's Lamictal Tablets would be free from generic competition for at least a five-year period. Subsequently, GSK received approval for a new label indication for the adjunctive treatment of Lennox-Gastaut syndrome in pediatric and adult populations. As part of that approval, Lamictal Tablets were awarded a seven-year orphan drug exclusivity ("ODE"), commencing on August 24, 1998. Congress enacted the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982), in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions. The Orphan Drug Act establishes a seven-year ODE period during which no ANDA for the same use of a generic version of the drug can be approved. 21 U.S.C. §360cc. However, ODE is indication-specific, meaning that the FDA can approve an ANDA for non-ODE protected uses during the seven-year period. The ODE for Lamictal Tablets expired on or about August 24, 2005, although since Lamictal Tablets were approved for other non-ODE protected indications, ANDAs could be approved for the non-ODE protected indications prior to August 24, 2005.

56. GSK received FDA approval of its NDA for Lamictal Chewables in August 1998, and received a three-year marketing exclusivity for this drug. During this three-year period, generic versions of this drug could not receive ANDA approval. ODE also applied to Lamictal Chewables, but was subject to the same restrictions as concerns Lamictal Tablets noted above.

57. The '017 patent, which expired on July 22, 2008, was (and has been) the only patent listed in the Orange Book for Lamictal Tablets. The '017 patent, along with another patent (U.S. Patent No. 5,698,226), were listed in the Orange Book as pertaining to Lamictal

Chewables, although as alleged below, this second patent played no role in the Patent Litigation between GSK and Teva. In addition, in 2007 (well after execution of the Agreements between GSK and Teva at issue here) GSK received a 6-month Pediatric Exclusivity, which is a regulatory exclusivity that prevents the FDA from approving the generic product until six months after (1) the expiration of the last-expiring valid, infringed, and enforceable patent listed in the Orange Book, or (2) regulatory exclusivity in existence at the time of the granting of the Pediatric Exclusivity, whichever is later. The application of Pediatric Exclusivity is determined on an ANDA-by-ANDA basis in the following respects: (a) Pediatric Exclusivity will not attach to the end of a patent as concerns any ANDA that contains a Paragraph IV certification to the patent; and (b) Pediatric Exclusivity will not attach to the end of a patent as concerns any ANDA that has been found not to infringe the patent. Here, with the granting of Pediatric Exclusivity, the total exclusivity for Lamictal Tablets ended in January 22, 2009, but only as concerns those ANDAs that (unlike Teva's) did not contain Paragraph IV certifications to the '017 patent. As to Teva's ANDA for Lamictal Tablets, the Pediatric Exclusivity was not a bar to the FDA granting final approval on August 30, 2006 (see below), even though the '017 patent expired in July 2008.

58. On or about April 1, 2002, Teva filed ANDA No. 76-388, seeking approval to manufacture and sell a generic version of Lamictal Tablets. A short time later, Teva filed ANDA No. 76-420, seeking approval to manufacture and sell a generic version of Lamictal Chewables. Teva's ANDAs were accompanied by Paragraph IV certifications which stated that every claim, except claim 5, of the '017 patent was invalid, unenforceable, and/or not infringed by Teva's proposed generic lamotrigine products. Claim 5, which purported to cover an injectable solution containing lamotrigine, was not at issue since Teva was not seeking FDA approval to sell an injectable version of lamotrigine. Teva also filed a Paragraph IV certification to the second

patent listed in the Orange Book regarding Lamictal Chewables. Since Teva was the first generic firm to file substantially complete ANDAs for AB-rated generic equivalents to Lamictal Tablets and Lamictal Chewables with Paragraph IV certifications to the '017 patent, Teva was entitled to separate 180-day exclusivities for generic versions of Lamictal Tablets and Lamictal Chewables, during which time no other generic manufacturers could sell generic versions of Lamictal Tablets or Lamictal Chewables pursuant to an ANDA (although GSK had the legal right to sell authorized generic versions of the products through its NDAs).

59. The FDA ultimately approved Teva's ANDA for lamotrigine chewables on June 21, 2006 and Teva's ANDA application for lamotrigine tablets on August 30, 2006. In so doing, the FDA found that: (a) Teva's lamotrigine chewables are bioequivalent to GSK's Lamictal Chewables – i.e., that Teva's lamotrigine chewables have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Chewables of the same dosage strengths; and (b) Teva's lamotrigine tablets have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Tablets of the same dosage strengths.

B. The Patent Litigation and Settlement

60. Soon after filing its ANDAs and Paragraph IV certifications, Teva sent GSK notifications of the Paragraph IV certifications as required by the regulations. Within 45 days of receiving Teva's Paragraph IV certifications to the '017 patent, GSK filed Civil Action No. 02-3779 and Civil Action No. 02-4537 against Teva in federal court in New Jersey in 2002, alleging that Teva's two ANDAs infringed the '017 patent. The two patent lawsuits were consolidated in November 2002. Both suits were filed within 45 days of receipt of the Paragraph IV notices from Teva, entitling GSK to automatic 30-month stays of approval of both of Teva's ANDAs. GSK did not sue Teva with respect to the second patent listed for Lamictal Chewables.

61. Following discovery, the Patent Litigation proceeded to a bench trial before Judge Bissell from January 18 to January 27, 2005. By this time, the 30-month stays of regulatory approval on both of Teva's ANDAs had either expired or were about to expire, i.e., the stay on Teva's tablet ANDA expired on December 26, 2004, while the stay on Teva's chewable ANDA was set to expire on February 16, 2005. Teva, however, still had not received final approval for either of its Lamictal ANDAs due ostensibly to outstanding safety and efficacy issues that had yet to be resolved to the FDA's satisfaction.

62. On the final day of trial, Judge Bissell ruled from the bench that Teva succeeded in establishing — by clear and convincing evidence — that Claim 1 of the '017 patent, which claimed the chemical compound 3,5-diamino-6-(2,3-dichlorophenyl)-l,2,4-triazine, was invalid as anticipated by the prior art.

63. In light of Judge Bissell's invalidity ruling, Teva was highly likely to succeed in invalidating the remaining asserted claims of the '017 patent, which included Claims 3, 4 and 6-12, based on its obviousness-type double patenting theory. That is, Judge Bissell's ruling that the chemical compound recited in Claim 1 was anticipated by the prior art, severely weakened GSK's validity positions with respect to the remaining asserted claims, as explained further below.

64. Before Judge Bissell, Teva argued that each of the remaining asserted claims were invalid because of GSK's "double patenting" of the claimed subject matter. Obviousness-type double patenting prohibits a party (such as GSK) from obtaining an improper extension of its patent rights by obtaining claims in a later patent that are not patentably distinct from claims in an earlier patent. In essence, Teva's obviousness-type double patenting theory alleged that the remaining asserted claims of the '017 patent were not patentably distinct from another GSK-

owned patent that issued four years before the '017 patent. The earlier GSK patent, U.S. Patent No. 4,311,701 ("the Roth patent"), similarly claimed, inter alia, "[a] method of treatment of convulsions" using a related chemical compound (i.e., 3,5-diamino-6-(2-chlorophenyl)-1,2,4-triazine). The Roth patent, however, expired on August 16, 1999, many years before the expiration of the '017 patent. The remaining asserted claims of the '017 patent could not be considered patentably distinct from the claims of the earlier Roth patent, if the remaining asserted claims were determined to be obvious in view of the Roth claims. Each of the remaining asserted claims of the '017 patent recited a method of treating convulsions or epilepsy using the chemical compound recited in Claim 1, or recited "an effective anticonvulsant amount" of the chemical compound recited in Claim 1. After the Court ruled that Claim 1 of the '017 patent was invalid as anticipated (and accordingly, the chemical compound 3,5-diamino-6-(2,3-dichlorophenyl)-l,2,4-triazine was in the prior art), then it was highly likely that the remaining asserted claims would have been obvious in view of the Roth claims.

65. Prior to the Court's ruling, both GSK and Teva recognized the significant impact a ruling that Claim 1 was anticipated would have on the validity (or lack thereof) of the remaining asserted claims. In fact, during closing arguments, GSK itself told the Court that Teva's "double patenting defense is premised on the fact that it wins on anticipation of Claim 1," a position which GSK described as "Teva's position pretrial." GSK further acknowledged that Teva's double patenting defense as to the remaining asserted claims required that "Teva passed the first hurdle on anticipation." Once that first hurdle on anticipation was surmounted by the Court's ruling, GSK and Teva should have known that an invalidity ruling as to each of the remaining asserted claims was highly likely.

66. On the final day of trial, Judge Bissell also indicated that he would endeavor "in the course of the next week" to reach a determination on the validity of the remaining asserted claims. An imminent ruling on the remaining asserted claims raised concerns for both parties: (1) for Teva, that a final court decision could lead to the triggering of its 180-day exclusivity period for its generic version of Lamictal Tablets and Lamictal Chewables before Teva had received final FDA approval; and (2) for GSK, that generic entry may be imminent for GSK's valuable Lamictal Tablet product.

(1) A Court Decision Would Dramatically Affect the Market for Lamictal Tablets and the Market for Lamictal Chewables

67. Assuming, as the parties must have in light of the Court's invalidation of Claim 1, it was highly likely that Teva would prevail in demonstrating the asserted claims of the '017 patent were invalid, then Teva would have been permitted to start selling its products immediately upon FDA approval, which was ultimately granted in 2006. Notably, because Teva was sued under the same patent claims and patent infringement theories for its generic versions of both Lamictal Tablets and Lamictal Chewables, its chances of invalidating the asserted claims were the same for its generic versions of both products.

68. Moreover, the successful invalidation of the asserted claims of the '017 patent would dramatically change the competitive landscape for both GSK and Teva. Under the applicable statutory regime, Teva's 180-day exclusivity period would begin to run from the earlier of either: (1) Teva's first commercial marketing of either generic product (although a launch of generic Lamictal Tablets would not trigger the 180-day period on generic Lamictal Chewables, and vice versa); or (2) a final court decision holding the '017 patent invalid, unenforceable, or not infringed regardless of whether Teva had commenced sales. Thus, the entry of a final court decision invalidating the asserted claims of the '017 patent would start the

clock on Teva's 180-day exclusivity period for that patent even if Teva did not have FDA-approval to sell the product(s).

69. Moreover, the invalidation of the asserted claims of the '017 patent would open the floodgates of generic competition for Lamictal Tablets and generic competition for Lamictal Chewables because within six months after such final decision invalidating the asserted claims other generics would be permitted to start selling their AB-rated generic products upon receiving FDA final approval. Also, if the asserted claims of the '017 patent were invalid, Pediatric Exclusivity would not apply to prevent FDA approval of all ANDA applications by other generic manufacturers of either Lamictal Tablets or Chewables. The Pediatric Exclusivity does not attach to the end of any patent that has been found to be invalid or unenforceable, and it does not apply to any ANDA applications that are accompanied by a Paragraph IV certification that the patent is invalid or not infringed by the proposed ANDA product unless and until there is a court decision which affirmatively holds that the patent is both valid and infringed by the ANDA product at issue.

(2) <u>It Would Be to GSK's Financial Disadvantage If the Court Invalidated the Patent</u>

70. The invalidation of all of the asserted '017 patent claims posed risks to both GSK and Teva. GSK faced the danger that if the court invalidated the other patent claims (which was highly likely), there would be a dramatic reduction in future revenue due to the loss of patent exclusivity of Lamictal Tablets and Lamictal Chewables. The highly likely probability that Teva would win the trial also placed Teva in a quandary because a successful final court decision would trigger the beginning of Teva's 180-day exclusivity period for its generic Lamictal Tablets and Lamictal Chewables prior to receiving FDA approval, which meant that Teva would lose some (if not all) of its valuable exclusivity. As alleged above, Teva's ANDA application for

generic lamotrigine chewables did not receive final approval until June 21, 2006 and its ANDA application for generic lamotrigine tablets did not receive final approval until August 30, 2006. Accordingly, if the January 2005 bench trial resulted in a final court decision before December 2005, then Teva's 180-day exclusivity would be triggered by a court decision and expire for both generic Lamictal Tablets and generic Lamictal Chewables before Teva could even bring those products to market. Any other competing generic that had final approval of their ANDAs for generic versions of Lamictal Tablets or Lamictal Chewables as of June 2006 (after Teva's exclusivity period had expired) could enter the market before (or at the same time) as Teva. So, Teva faced the risk that if its 180-day exclusivity ended before its product was approved another rival's product might enter the market before Teva's, thereby gaining not only the significant profits during that period but also the long-term "first-mover" advantage.

71. Thus, GSK had an interest in delaying Teva's generic Lamictal Tablets entry for as long as possible so that GSK could continue to earn monopoly profits on Lamictal Tablets.

72. Recognizing the risks to both parties (i.e., that it was highly likely that GSK would lose its patent protection entirely and that Teva might not be permitted to take full advantage of its success), the parties immediately started settlement negotiations, and on February 2, 2005, the parties had a conference with the Court during which they asked the Court to refrain from ruling on the validity of the remaining claims.

73. Two weeks following that conference, GSK and Teva reached a settlement, the terms of which are set forth in the Agreements. The Settlement Agreement expressly provides that the inducements set forth in the Agreements are part of the "consideration" that GSK offered Teva "in reaching agreement to settle."

74. The settlement permitted Teva to sell limited amounts of generic lamotrigine

chewables in the United States under terms unduly favorable to Teva, by no later than June 1, 2005 – approximately 37 months prior to the expiration of the '017 patent. Even though Teva's ANDA to sell its generic version of Lamictal Chewables did not receive final approval from the FDA until June 2006, GSK supplied Teva with chewable lamotrigine product, which Teva began selling as an authorized generic on May 25, 2005.

75. Under the Agreements, GSK additionally granted Teva: (a) a royalty-free, non-transferable license under the '017 patent to import, manufacture, have manufactured and have sold Teva's generic version of Lamictal Tablets in the United States,[3] starting on July 21, 2008, at 5:00 p.m. Pacific time, which was when the '017 patent expired; and (b) a waiver of any potential Pediatric Exclusivity applicable to Teva's generic version of Lamictal Tablets. Even if GSK ultimately received Pediatric Exclusivity, it would have little or no value – such exclusivity would not apply against Teva unless Judge Bissell found the '017 patent valid and infringed by Teva's ANDA products prior to Teva entering the market. Thus, Pediatric Exclusivity as to Teva's ANDA was at best a conditional, theoretical right which could not ripen, because at the time of the Agreements, the court did not enter a judgment finding the '017 patent valid and infringed. In fact, at the time of the Agreements, no Pediatric Exclusivity had been granted to GSK by the FDA (it was received in 2007 after the FDA finally approved Teva's generic Lamictal Tablet, and after Teva's generic Lamictal Tablet could have been on the market but for the Agreements – and it could not have applied to Teva). Thus, even though Teva had already succeeded in invalidating the claim covering the chemical compound lamotrigine, which is the active ingredient of Lamictal, and even though it was highly likely that the Court would invalidate the patent's other asserted claims, the settlement had no procompetitive benefit

[3] Includes Puerto Rico.

because it gave little or no discount or reduction to the patent's exclusionary power (i.e., Teva agreed to settle without gaining any right to enter with its generic version of Lamictal Tablets prior to the patent's expiration).

76. Furthermore, even though Teva's generic versions of both Lamictal Tablets and Lamictal Chewables were subject to the same patent claims (and thus, Teva's chances of litigation success were the same for both products), Teva was allowed to start selling a generic version of the significantly smaller product within three months after the settlement, while it agreed to wait at least three years (until the expiration of the patent term) to start selling a generic version of the more than $2 billion a year product. The significantly different entry dates reflect the fact that the parties did not structure the settlement to reasonably reflect the probability that Teva would successfully invalidate all asserted claims of the patent. Rather, it reflects the reality that Teva was given financial inducements to delay entry of its generic Lamictal Tablet product.

77. Because Teva's generic version of Lamictal Chewables were AB-rated only to the low-dosage strength branded Lamictal Chewables and were not AB-rated to Lamictal Tablets, the generic version of Lamictal Chewables that Teva sold could not be substituted for branded Lamictal Tablets, and thus prior to July 2008 Teva could not provide lower-priced generic substitutes for Lamictal Tablets that would: (a) be broadly substituted for the higher-priced Lamictal Tablets, or (b) otherwise efficiently compete with branded Lamictal Tablets. Furthermore, the agreement to delay Teva's generic version of Lamictal Tablets from entering the market until after the close of business on July 21, 2008 and GSK's agreement to refrain from launching its own authorized generic Lamictal Tablet until January 2009 had no procompetitive benefit because GSK was conferring rights under the Agreements which were beyond the exclusionary scope of the '017 patent, which expired in July 2008.

78. Teva received significant consideration, incentives, and benefits in exchange for its agreement to delay generic lamotrigine tablet entry by: (a) abandoning its efforts to invalidate the asserted claims of the '017 patent; and (b) not competing against GSK's Lamictal Tablets with a less-expensive generic version until the '017 patent expired. First, Teva was permitted to enter the U.S. market within a few months with a GSK-supplied authorized generic version of the much smaller Lamictal Chewables product under terms unduly favorable to Teva. In pleadings from a subsequent Teva-GSK litigation, GSK acknowledged that its agreement allowing Teva to enter in three months with a generic version of the smaller Lamictal Chewable product "formed part of the bargain between GSK and Teva" and was one of the "benefits" that Teva received for agreeing to abandon its efforts to invalidate the '017 patent.

79. Second, because Teva was not ready to take advantage of its 180-day marketing exclusivity in January 2005, the agreement to delay entry virtually guaranteed Teva the right to use all or most of its 180-day exclusivity periods for Lamictal Tablets. GSK also benefitted because the Agreements delayed not only the entry of Teva but other generics as well. Thus, by and through these Agreements, Teva and GSK afforded themselves a mutually beneficial guarantee of higher revenues at the expense of their customers.

80. In addition, GSK agreed not to launch authorized generic Lamictal Tablets until January 2009 (i.e., 180 days after Teva was on the market with Lamictal Tablets, and over three years after Teva was on the market with Lamictal Chewables). This constituted a large payment to Teva for which there can be no redeeming procompetitive justification. At the time these Agreements were drafted, a pharmaceutical company such as GSK that marketed a brand-name drug under an NDA would often introduce – either by itself or through an affiliate – an authorized generic at the same time generic entry was anticipated. As of 2005, GSK had a

history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. *See supra* at paragraph 26.

81. A brand company's launch of an authorized generic is extremely damaging to any first-filer generic, such as Teva, because it results in lost market share (i.e., fewer units sold), reduced profits because price competition between the generic and authorized generic forces down prices, and a reduction in the generic's long-term "first mover advantage." As the FTC noted in a June 2009 report on Authorized Generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [Authorized Generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [Authorized Generic]."

82. Notably, while a brand company can lower the prices on its brand products following generic entry (which was an option left open to GSK under the Agreements), that option does not present the same danger to a generic such as Teva, and does not result in the same savings to purchasers. Lowering the price of the brand product is a strategy that a company may use to attempt to retain brand sales upon generic entry, in addition to and together with launching an authorized generic. Because many states have regulations that either require or strongly encourage pharmacists to automatically fill prescriptions with only an AB-rated generic version of a drug in most situations, even if an NDA holder (such as GSK) lowers the price of its brand drug, state regulations are a barrier that prevent or impede the branded drug from being used for most prescriptions. The result is that most of a generic's sales volume is unaffected by a reduction in the brand price and the generic does not feel the same competitive pressure to lower its prices in response to a drop in the branded price (in contrast to the situation where a branded company launches an authorized generic). Thus, while an NDA holder can try to compete

against a generic drug through various means other than launching an authorized generic, those competitive options are far weaker and do not provide nearly the consumer savings and benefits as the launch of a true authorized generic. Consequently, GSK's agreement to restrict its competitive responses to far less effective, secondary options was an illegal, anticompetitive agreement by which the parties agreed to restrict until January 2009 competition that would undermine Teva's prices, and consequently resulted in overcharges to purchasers.

83. Indeed, in its June 2009 report regarding Authorized Generics, the FTC expressly concluded that a generic manufacturer might agree to delay the sale of its generic product in exchange for a brand company's agreement (such as the one involved here) to not launch an authorized generic to consumers' detriment:

> To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – during the generic's 180 days of marketing exclusivity…Such agreements can harm consumers . . . .

84. According to Teva's pleadings in a 2008 litigation regarding these products, during the settlement negotiations GSK and Teva specifically considered the possibility that GSK might want to sell an authorized generic during Teva's six-month exclusivity periods, but the parties agreed that GSK would not be permitted to do so. According to Teva, GSK's agreement to not launch an authorized generic until January 2009 was a critical and central consideration for Teva's acceptance of the settlement and delayed entry dates for generic Lamictal Tablets. For example, Teva stated in the 2008 litigation that GSK's agreement to not compete against Teva by selling an authorized generic during the first 180 days in which Teva was selling generic Lamictal Tablets was:

> **[A]n important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was**

asserting against GSK in the Patent Litigation.

* * *

. . . the **key consideration** Teva bargained for in [the License and Supply Agreement]. (Emphasis added).

85. GSK's agreement to not launch its own authorized generic Lamictal product(s) before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

86. Thus, according to Teva, GSK's agreement to not launch an authorized generic was a "key" and "important" consideration of Teva's decision to relinquish its attacks on the '017 patent's validity. Indeed, Teva received more from the settlement than it would have received if it had won the patent litigation. That is, Teva extracted, among other things, a market allocation agreement that entitled it to the entire generic market for Lamictal Tablets for its 180-day exclusivity period.

87. Absent GSK's illegal agreement to refrain from competing against Teva by selling an authorized generic prior to January 2009 (and absent the valuable financial inducements alleged above), Teva would have sought and obtained an entry date for its generic version of Lamictal Tablets earlier than the entry date it accepted in the Agreements.

Alternatively, Teva would have prevailed in the patent litigation against GSK and would have launched generic Lamictal Tablets immediately thereafter. As Teva acknowledged in its pleadings in the subsequent litigation, Teva believed that GSK's agreement to not launch an authorized generic was critical because Teva was only getting a short period of time to sell its generic Lamictal Tablet product before other generics were free to enter the market. As Teva stated, GSK's agreement to refrain from competing against Teva by selling an authorized generic prior to January 2009 was:

> **critical here, because the benefit conferred to Teva from this License Agreement was of such a short duration.** GSK's pediatric exclusivity under its patent was to expire on January 22, 2009. . . . Thus, **the benefit to Teva of the License Agreement was a brief, six-month window in which it would be the first and only supplier of generic lamotrigine.**

(emphasis added).

88. On April 4, 2005, the parties filed a Stipulation and Order of Dismissal in the Patent Litigation seeking the dismissal of all claims and counterclaims. On the same day the Court signed the dismissal, it also entered an order withdrawing the bench ruling that invalidated Claim 1 of the '017 patent.

C. Teva's Exclusive Launch of Generic Lamotrigine Tablets

89. Despite having received FDA approval to launch lamotrigine tablets almost two years earlier, Teva delayed launching its generic version of Lamictal Tablets until after the close of business on July 21, 2008 (the earliest date permitted under the terms of the Agreements with GSK).

90. Pursuant to the Agreements between GSK and Teva, GSK did not launch its own authorized generic of either Lamictal Tablets or Lamictal Chewables in competition with Teva prior to January 2009.

91. Although Teva has alleged in the subsequent litigation that GSK implemented a scheme to slow Teva's market penetration for its generic version of Lamictal Tablets, none of GSK's conduct had the effect of constraining or reducing the pricing of Teva's generic Lamictal Tablets during the exclusivity period in the same way or to as great a magnitude that competition from an authorized generic would. In addition, GSK would have both engaged in a scheme to slow Teva's market penetration for generic Lamictal Tablets and also launched authorized generic Lamictal Tablets absent GSK's promise not to launch an authorized generic, which would have caused generic prices to be lower during Teva's exclusivity period than they actually were.

92. GSK's agreement not to launch authorized generic Lamictal Tablets during Teva's 180-day market exclusivity period enabled Teva to generate many millions of dollars of additional revenue at the expense of purchasers who would have paid lower prices for generic lamotrigine tablets had GSK launched an authorized generic.

93. Because of Teva's 180-day exclusivity on generic versions of Lamictal Tablets, which was secured by and through the anticompetitive Agreements at issue, no other generic was allowed to launch, and none in fact did launch, prior to January 22, 2009. By the end of January 2009, at least three other firms (i.e., Mylan, Watson, and Dr. Reddy's) launched generic versions of Lamictal Tablets.

D. Defendants' Conduct Delayed Generic Competition and Enabled Defendants to Wrongfully Charge Supra-Competitive Prices for Lamotrigine Tablets

94. Teva's 180-day exclusivity period for its generic version of Lamictal Tablets would have been triggered earlier if GSK and Teva had not agreed to delay entry of Teva's generic Lamictal Tablets product until July 22, 2008 because (a) absent the inducements GSK gave Teva, the settlement would have provided for an earlier entry of Teva's less expensive

generic version of Lamictal Tablets in 2007; or (b) Teva would have launched its generic Lamictal Tablet product in August or September 2006, upon receipt of final FDA approval after successfully invalidating the asserted claims of the '017 patent (which was highly likely). Instead, because of the unlawful Agreements, Teva did not enter until July 2008, leaving its 180-day exclusivity in place and thereby blocking final FDA approval and entry of other generic versions of Lamictal Tablets until January 2009.

95. The Agreements between Teva and GSK guaranteed that Teva's generic exclusivity period for generic Lamictal Tablets would not be triggered by a final court decision before Teva received FDA approval of that ANDA, and provided Teva with the full 180 days of exclusive generic sales on that product.

96. The Agreements between Teva and GSK guaranteed that GSK would have three more years of exclusivity on the blockbuster Lamictal Tablet product with no generic competition for the entire patent term even though it was highly likely that the remaining patent claims would have been invalidated in 2005.

97. In exchange for Teva's delaying its launch of its generic version of the Lamictal Tablet until close of business on July 21, 2008, Teva secured: (1) the right to almost immediately launch a GSK-supplied generic Lamictal Chewable product under terms favorable to Teva, which generated profits for Teva, but created much smaller consumer savings and benefits than an earlier launch of the Lamictal Tablet product (i.e., any consumer welfare generated by the earlier launch of generic lamotrigine chewables pales in comparison to the consumer harm created by the anticompetitive delay in entry of the generic lamotrigine tablets); (2) a guarantee on its ability to fully exploit its 180-day exclusivity period relating to its generic version of Lamictal Tablets; and (3) GSK's agreement not to compete with Teva by not

marketing an authorized generic for both Lamictal Tablets and Lamictal Chewables until January 2009.

98. Defendants' unlawful conduct, therefore, delayed not only the launch of less expensive generic versions of Lamictal Tablets, but prevented GSK's launch of authorized generic products in competition with Teva's generic versions of Lamictal Tablets and Lamictal Chewables prior to January 2009.

99. Moreover, the Agreements between GSK and Teva which delayed Teva's launch of the generic Lamictal Tablets and guaranteed Teva's exclusivity period on that product without competition from a GSK authorized generic were not necessary for the settlement of the Patent Litigation and constitute an ancillary restraint of trade.

VI. EFFECT ON INTERSTATE COMMERCE

100. At all material times, Lamictal Tablets, manufactured and sold by GSK, and generic versions of Lamictal Tablets manufactured by Teva, were shipped across state lines and sold to customers located outside its state of manufacture.

101. During the relevant time period, in connection with the purchase and sale of Lamictal Tablets (and Teva's generic versions of Lamictal Tablets), monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

102. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

VII. RELEVANT MARKET

103. Direct proof exists that GSK had monopoly power over the price of lamotrigine tablets and their AB-rated generic equivalents. Such direct evidence includes, *inter alia*: (a) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in lamotrigine tablet prices upon entry of AB-rated generic lamotrigine tablets that had not occurred until generic entry; and (b) abnormally high price-cost margins enjoyed by GSK prior to the entry of such generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether GSK had monopoly power.

104. Even at their monopoly price, Lamictal Tablet products do not exhibit significant, positive cross-elasticity of demand with respect to price with any products other than AB-rated generic versions of Lamictal Tablets.

105. Lamotrigine Tablets – i.e. brand and generic Lamictal Tablets (in all its forms and dosage strengths) – constitute a separate and distinct product market. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lamotrigine tablets are prescribed.

106. At all relevant times, GSK enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

107. Through the anticompetitive conduct alleged herein, GSK was able to profitably

charge supra-competitive prices for Lamictal Tablets without losing substantial sales, and thus, by definition, maintained monopoly power with respect to Lamictal Tablets sold in the United States.

108. GSK's market share in the relevant market was 100% until the entry of AB-rated generics.

VIII. FIRST CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)
(CONSPIRACY TO DELAY GENERIC COMPETITION FOR LAMICTAL TABLETS)

109. Plaintiffs incorporate and re-allege 1 to 108 of the foregoing Paragraphs herein, as though fully set forth below.

110. Beginning in or about February 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of lamotrigine tablets in the United States to GSK until July 21, 2008; (b) fix the price at which Plaintiffs would pay for lamotrigine tablets at the higher, branded price during that period; and (c) prevent the sale of generic versions of lamotrigine tablets other than Teva's (including GSK's authorized generic versions) in the United States until at least January 22, 2009.

111. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic lamotrigine tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree

to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

112. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "rule of reason" mode of analysis.

113. Plaintiffs have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiffs have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets.

114. As a result of Defendants' illegal conduct, Plaintiffs paid more than they would have paid for lamotrigine tablets absent Defendants' illegal conduct. But for Defendants' illegal conduct, Teva's generic Lamictal Tablets product and GSK's authorized generic Lamictal Tablets product would have launched well before July 2008.

115. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalent.

116. During the relevant period, Plaintiffs purchased substantial amounts of Lamictal

Tablets directly from GSK and/or their generic equivalent directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiffs paid prices for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Plaintiffs were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.

IX. SECOND CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)
(CONSPIRACY NOT TO COMPETE WITH GENERIC LAMICTAL TABLETS)

117. Plaintiffs incorporate and re-allege 1 to 108 of the foregoing Paragraphs herein, as though fully set forth below.

118. Beginning in or about February 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, in which GSK agreed to not sell its competing authorized generic version of Lamictal Tablets until at least January 22, 2009.

119. As alleged above, as of 2005, GSK had a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. Moreover, while GSK's use of DAW5 codes (also known as "dispense as written codes") and discounts to certain retailers did not significantly constrain or reduce the price of Teva's generic Lamictal Tablets, the fact that GSK used DAW5 discounts to ineffectively compete against Teva's generic Lamictal Tablets evidences that GSK was

motivated, but for the anticompetitive Agreements, to price compete against Teva's generic lamotrigine tablets product. Consequently, but for Defendants' illegal conduct, GSK would have both sold its authorized generic version of Lamictal Tablets starting in July 2008 (or earlier if Teva had started selling its generic version of Lamictal Tablets earlier) and pursued the contracting strategy (the DAW5 discount strategy).

120. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic versions of Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

121. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "rule of reason" mode of analysis.

122. Defendants' agreement that GSK would not launch an authorized generic version of Lamictal Tablets until after January 2009 did not constitute GSK's unilateral exercise of any legitimate patent power. As an initial matter, GSK's decision not to launch an authorized generic was not the result of GSK's unilateral decision but one that was made at a rival's request

as consideration for the rival's agreement to stay off the market until July 2008. Furthermore, GSK's collusive agreement to constrain how it competed against Teva was not an exercise of any patent power GSK had to exclude Teva, but rather GSK's agreement to exclude its own generic product that it would have otherwise sold. Thus, the agreement has nothing to do with whether or how GSK exercised its patent powers but its agreement to limit its ability/willingness to compete. Moreover, the agreement that GSK would not launch an authorized generic to compete against Teva encompassed the period from July 2008 through January 2009, after the '017 patent had expired and during a period in which no other GSK exclusivities barred Teva from the market. So pursuant to the illegal agreement, GSK withheld its authorized generic from the market during a period that was outside the temporal scope of the '017 patent and/or any other exclusivities that applied to Teva.

123. Plaintiffs have been injured in their business and property by reason of Defendants' unlawful contract, combination, and conspiracy. Plaintiffs have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets.

124. As a result of Defendants' illegal conduct, Plaintiffs paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. Had GSK launched an authorized generic version of Lamictal Tablets (as it was motivated to do), Plaintiffs would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalents.

125. During the relevant period, Plaintiffs purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalent directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablets. Plaintiffs paid prices for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Plaintiffs were deprived of the opportunity to purchase lower-priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Plaintiffs were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of brand-name Lamictal Tablets were artificially inflated by Defendants' illegal conduct.

X. THIRD CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)
AGAINST GSK ONLY
(MONOPOLIZATION OF LAMICTAL TABLETS MARKET)

126. Plaintiffs incorporate and re-allege 1 to 108 of the foregoing Paragraphs in this Complaint, as though fully set forth below.

127. Defendant GSK used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the lamotrigine tablet market, as detailed above.

128. GSK combined, conspired and contracted with Teva to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and GSK did in fact monopolize trade in the United States in the market for lamotrigine tablets, and to eliminate competition in the sale of Lamictal Tablets and their generic equivalents in the United States.

129. The goal, purpose and/or effect of GSK's scheme was also to maintain and extend

GSK's monopoly power with respect to lamotrigine tablets. GSK's illegal scheme to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lamictal Tablets enabled GSK to continue charging supra-competitive prices for lamotrigine tablets without a substantial loss of sales.

130. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry for generic versions of Lamictal Tablets, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

131. As a result of GSK's illegal conduct, Plaintiffs paid more than they would have paid for lamotrigine tablets, absent GSK's illegal conduct. But for GSK's illegal conduct, Teva's generic Lamictal Tablets product and GSK's authorized generic Lamictal Tablets product would have launched well before July 2008 causing prices to be lower.

132. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine tablet requirements, and/or would have received lower prices on some or all of their remaining

purchases of GSK's Lamictal Tablets and/or Teva's generic equivalents.

133. During the relevant period, Plaintiffs purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalents directly from Teva. As a result of GSK's illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiffs paid prices for lamotrigine tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein because: (1) Plaintiffs were deprived of the opportunity to purchase lower priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Plaintiffs were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of branded Lamictal Tablets was artificially inflated by GSK's illegal conduct.

134. GSK's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for lamotrigine tablets in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XI. FOURTH CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)
(CONSPIRACY TO MONOPOLIZE LAMICTAL TABLETS MARKET)

135. Plaintiffs incorporate and re-allege 1 to 108 and 126 to 134 of the foregoing Paragraphs in this Complaint, as though fully set forth below.

136. GSK and Teva combined, conspired and contracted to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and GSK and Teva did in fact conspire to monopolize trade in the United States in the market for lamotrigine tablets, and to eliminate competition in the sale of Lamictal Tablets and their generic equivalents in the United States.

137. The goal, purpose and/or effect of GSK and Teva's conspiracy was also to

maintain and extend GSK's monopoly power with respect to lamotrigine tablets. GSK and Teva's illegal conspiracy to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lamictal Tablets enabled GSK to continue charging supra-competitive prices for lamotrigine tablets without a substantial loss of sales.

138. GSK and Teva committed overt acts in furtherance of the conspiracy including, *inter alia*, GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009, which was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablet. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

139. As a result of GSK and Teva's illegal conduct, Plaintiffs paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. But for GSK and Teva's illegal conduct, Teva's generic Lamictal Tablets product and GSK's authorized generic Lamictal Tablets product would have launched well before July 2008 causing prices to be lower.

140. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs would have substituted lower-priced generic lamotrigine

tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine tablet requirements, and/or would have received lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalents.

141. During the relevant period, Plaintiffs purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalents directly from Teva. As a result of GSK and Teva's illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiffs paid prices for lamotrigine tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein because: (1) Plaintiffs were deprived of the opportunity to purchase lower priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Plaintiffs were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of branded Lamictal Tablets were artificially inflated by GSK and Teva's illegal conduct.

142. GSK and Teva's illegal conduct had an effect on interstate commerce as alleged in paragraphs 100 to 102 above.

143. GSK and Teva's conduct was in the aggregate a conspiracy undertaken with the specific intent to monopolize the market for lamotrigine tablets in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for judgment against all Defendants, jointly and severally, as follows:

1. That the Court adjudge and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;

2. That the Plaintiffs be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

3. That the Plaintiffs be awarded reasonable attorneys' fees and costs; and

4. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in this Complaint so triable.

Respectfully Submitted,

Dated: February 2, 2023

By: _____

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